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MINIREVIEW

Bringing HIV Self-Testing to Scale in the United States: a Review of Challenges, Potential Solutions, and Future Opportunities

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ABSTRACT HIV self-testing (HIVST) provides an at-home option to counter the barriers that patients face with testing performed in health care settings. HIVST has gradually increased in popularity in a time when social media and technology-based solutions are preferred. In this paper, we consider the aspects of self-testing that merit its integration into HIV testing and prevention systems in the United States. Several elements favor self-testing for large-scale implementation, including ease of use, convenience, potential for integration with mobile health (mHealth), and availability for various modes of distribution. HIVST has a demonstrated ability to reach at-risk individuals who otherwise rarely test. The paradigm of self-testing, however, introduces new challenges, including lesser test performance relative to that in health care settings, nonstandard counseling following receipt of test results, and difficulty in providing linkage to care. After discussing the performance of oral fluid versus blood-based HIVST, we review data regarding acceptability of HIVST, offer insights into counseling and linkage to care for HIVST, and provide examples of novel applications of and future research directions for HIVST.

KEYWORDS HIV, HIV testing, HIVST, home-testing, mHealth, oral fluid, public health, self-testing

HIV testing is a main point of entry into HIV care and prevention services. An estimated 1.2 million persons in the United States are living with HIV, with 14% (about 168,000) unaware of their infection status (1, 2). HIV self-testing (HIVST) circumvents some of the typical barriers to testing, such as inconvenience (e.g., transportation, time, and location), privacy concerns, and stigma (3). Addressing testing barriers through the provision of HIVST has the potential to increase HIV testing rates and reach those who are undiagnosed. Indeed, one of the central principles of the UNAIDS 90-90-90 campaign is for 90% of people with HIV worldwide to know their HIV status by 2020 (4). In order to meet HIV testing goals, novel avenues of testing, like HIVST, should be pursued by public health systems (4).

The current approach of the U.S. Centers for Disease Control and Prevention (CDC) to reduce new infections, the High-Impact HIV Prevention program, focuses on reducing transmission among key, high-risk populations, including gay and bisexual men, communities of color, women, people who use injection drugs, transgender men and women, and youths (5). Youths are targeted in part because they are among the most infrequently tested, with an estimated 60% of HIV-positive youths between 18 and 24 years old unaware of their HIV status (6). One of the advantages of HIVST is its potential to reach such key populations, as previous studies indicate a high acceptability and often a preference for HIVST among youth, men who have sex with men (MSM), racial/ethnic minorities, pregnant women, and transgender women (7–11).

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Although HIVST affords numerous advantages, it also introduces a number of challenges. The performance of HIVST interventions in other key populations, such as injection drug users and prisoners, is unclear due to limited research and programmatic data both internationally and in the United States. Financial barriers to HIVST are significant, as the only over-the-counter option, the OraQuick in-home HIV test, frequently has a retail cost of $40 (12). Other self-testing kits do not provide immediate results, due to a mail-in procedure, and moreover require online ordering, necessitating Internet access.

Nevertheless, HIVST possesses an unlocked potential to advance preventative health care and keep pace with the increasingly mobile-connected and home service-receiving public. To facilitate these potential benefits, the World Health Organization (WHO) has synthesized HIVST approval guidelines in order to catalyze the development of international HIVST policies and increase access to low-cost HIVST methods (13). Despite these efforts, the U.S. Food and Drug Administration (FDA) has approved only the OraQuick test, resulting in a monopoly and its attendant risks: the test has been described as underutilized by consumers and health agencies primarily due to its cost (3). Ordering test kits online that use a fingerstick device and filter paper card for self-collection, with the card mailed to a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory for testing, is another HIVST method (14, 15). To our knowledge, companies operating under this mechanism have not received FDA review for the procedure. In contrast to HIVST, HIV testing performed in a health care setting (clinic-based testing [CBT]) is seen as a public health good, with most routine testing provided at low or no cost. Additionally, societal expectations may be changing as individuals become accustomed to receiving services delivered to their homes. HIVST has the ability to reach more people and the potential to leverage technology-based solutions to link persons to care. Individuals hesitant to test for HIV in a health care facility may be ideal candidates for the provision of HIVST.

In this review, we assess the current literature that merits or cautions provision of HIVST. Several excellent studies have previously covered different HIV testing technologies (antibody, antigen, and nucleic acid), diagnostic algorithms, and considerations for test selection (16–20). The WHO has detailed guidelines on HIVST implementation (21), and a literature review has described HIVST through the lens of translational science (3). An exceptional literature review by Ibitoye et al. details the performance of unassisted HIVST methods and concerns regarding difficulty of blood-based HIVST (22). Our review focuses on challenges, potential solutions, and opportunities for scaling up HIVST in the United States by examining test performance (e.g., sensitivity and specificity), preferences for HIVST methods and future options, acceptability and willingness to pay for HIVST, pre- and posttest counseling, concerns for linkage to care, and technical innovations for implementation. Solutions and goals for the future to counter obstacles in HIVST are proposed based on the reviewed evidence.

ORAL FLUID VERSUS FINGERSTICK BLOOD TEST PERFORMANCE

Laboratory performance. HIVST performance may differ depending on whether an approach is assisted or unassisted and by whether the type of specimen collected is oral fluid or fingerstick blood. Assisted approaches involve a trained professional walking through an in-person demonstration of how to conduct the self-test and interpret the results, and unassisted approaches include only test instructions and/or a phone help line. In systematic reviews, assisted and unassisted HIVST approaches result in highly concordant test results, with fair to near perfect agreement between both approaches (23, 24). Moreover, the systematic review and meta-analysis of 25 studies from Figueroa et al. (24) concluded that individuals are able to achieve the same results as health care workers when administering self-tests.

While HIVST performances of unassisted and assisted methods do not differ significantly, there are substantial differences in sensitivity and specificity between oral fluid and blood-based self-test methods. Sensitivity refers to a test's ability to detect a true-positive result, and specificity refers to a test's ability to detect a true-negative

TABLE 1 List of commonly used HIV self-tests by specimen type, performance, current approval, and availability for purchase[a]

Self-test name	Generation, target analyte	Specimen	Sensitivity (%)	Specificity (%)	Approving body(ies)	Availability	Manufacturer name and location	Author(s) (reference no.)
OraQuick in-home HIV test (marketed as OraQuick HIV self-test in countries other than USA)	2nd, HIV-1/2 antibodies	Oral fluid	Asiimwe et al. (observed arm), 100; Asiimwe et al. (unobserved arm), 90; Chavez et al., 88.8; Pant Pai et al., 66.7; Sarkar et al., 100; FDA, 91.7; CE, 100; range = 66.7–100	Asiimwe et al. (observed arm), 99.1; Asiimwe et al. (unobserved arm), 95.1; Chavez et al., 100; Pant Pai et al., 100; Sarkar et al., 100; FDA, 99.98; CE, 99.6; range = 95.1–100	FDA, CE mark, WHO-PQ[b]	USA, Burundi, Kenya, South Africa, Uganda, Zambia, Zimbabwe	OraSure Technologies Inc., Bethlehem, PA (OraQuick in-home HIV test), manufactured in USA and assembled in Thailand (OraQuick HIV self-test)	WHO, Unitaid (12), Asiimwe et al. (62), Chavez et al. (63), Pant Pai et al. (64), Sarkar et al. (9), FDA (26)
INSTI HIV self-test	2nd, HIV-1/2 antibodies	Whole blood (fingerstick)	Gras et al., 96.2; Bwana et al., 98.99; CE (box), 100; CE (pouch), 99.8; range = 96.2–99.8	Bwana et al., 98.15; CE (box), 99.8; CE (pouch), 99.5; range = 98.15–99.8	CE mark, WHO-PQ	Europe, Nigeria	bioLytical Laboratories, Richmond, British Columbia, Canada	WHO, Unitaid (12), Gras et al. (65), Bwana et al. (59)
Atomo HIV self-test	3rd, HIV-1/2 antibodies	Whole blood (fingerstick)	CE, 99.7	CE, 99.7	CE mark	Kenya, South Africa	Atomo Diagnostics, Australia	WHO, Unitaid (12)
BioSURE HIV self-test	2nd, HIV-1/2 antibodies	Whole blood (fingerstick)	CE, 99.7	CE, 99.9	CE mark	South Africa, UK	BioSURE United Kingdom, Ltd., UK	WHO, Unitaid (12)
Exacto HIV screening test	3rd, HIV-1/2 antibodies	Whole blood (fingerstick)	Tonen-Wolyec et al., 100; CE, 99.99	Tonen-Wolyec et al., 99.2; CE, 99.90	CE mark	Europe	Biosynex Group, France	WHO, Unitaid (12), Tonen-Wolyec et al (66)
Autotest VIH	2nd, HIV-1/2 antibodies	Whole blood (fingerstick)	CE, 100	CE, 99.8	CE mark	15 European countries	AAZ-LMB, Boulogne-Billancourt, France	WHO, Unitaid (12)
DBS mail-in to laboratory	4th, HIV-1/2 antibodies, p24 antigen	Whole blood (fingerstick)	van Loo et al., 100	van Loo et al., 100	Unknown[c]	Online order (e.g., MyLabBox)	Various examples (e.g., myLAB Box, Los Angeles, CA)	van Loo et al. (34)

[a]Adapted from a Unitaid and WHO report (12) and updated to include data from a review by Figueroa et al. (24) and several additional recent studies (59, 66).

[b]WHO-PQ, WHO prequalification.

[c]Self-collected specimen, with test performed in approved laboratory after being mailed in. This test is conducted by a number of laboratories; it is unclear if this method falls under approval requirements of regulatory agencies.

result. The range of sensitivity estimates was higher for blood-based HIVST (96.2 to 100%) than for oral fluid HIVST (80 to 100%). Estimates of specificity were also higher for blood-based HIVST (99.5 to 100%) than for oral fluid HIVST (95.1 to 100%) (24). Table 1 lists more detailed information on test performance of HIVST methods that are either Conformité Européene (CE) marked or FDA approved. The table illustrates that sensitivity estimates of FDA-approved OraQuick test are overall lower and more variable than estimates for other tests that lack FDA approval.

Another consideration for HIVST performance is the proportion of results that are invalid because tests do not work properly (due to either user or manufacturer error) or yield results that are indeterminate and require repeat testing. Invalid results may be more common among blood-based HIVST (0.4 to 9.5%) than oral fluid HIVST (0.2 to 4.5%), potentially due to greater likelihood of insufficient self-collection of blood specimens relative to fluid specimens (24). In sum, blood-based HIVST have greater sensitivity and specificity than oral fluid HIVST yet potentially increased rates of invalid test results (24). The overall lower sensitivity and specificity of oral fluid HIVST than blood-based HIVST should be considered against its relative ease of use and other program considerations, such as acceptability in the target population.

The FDA-approved OraQuick in-home HIV test (OraSure Technologies, Bethlehem, PA) is a 2nd-generation assay, primarily detecting IgG antibodies. Some HIVST are 3rd-generation tests that detect both IgG and IgM antibodies, potentially permitting a shorter window period (12). The window period refers to the period between initial infection with HIV and the point at which sufficient time has passed for a test to be able to detect the infection. Self-collected blood specimens may be used for 4th-generation tests in systems where dried blood spot (DBS) cards are mailed into reference laboratories. The p24 antigen is detected in 4th-generation tests, resulting in a shorter window period. Oral fluid HIVST is disadvantaged for two reasons: one is the absence of p24 antigens (required for 4th-generation testing), and the other is the relative concentration of antibodies in oral fluid. Due to lower concentrations of antibodies, oral fluid HIVST cannot detect early stages of an HIV infection (25). Given these limitations, oral fluid HIVST (2nd generation) is estimated to have a 55-day window period (26); in contrast, window periods for blood-based markers are about 18 days for tests that assess p24 antigen (4th generation) and about 22 days for antibody only (3rd generation) tests (27).

Limitations of current studies on HIVST performance, pointed out by Figueroa et al., are a lack of data regarding study participants who were recently infected with HIV and inconsistent reference standards among studies. A reference standard is defined as any test that is used to determine true HIV status compared to the test being studied. Inconsistent and imperfect reference standards may lead to variable estimates of test sensitivity (24). Given the increased window period of oral fluid HIVST compared to often blood-based reference standards, it is important to consider how the window period might affect test sensitivity. Differential levels of testing within the window period may also account for variable estimates of sensitivity of oral fluid HIVST. To our knowledge, there is limited information on HIVST performance comparing samples collected before and after the window period. Future studies of HIVST performance should consider collecting data on timing of suspected infection, such as through a number of available assays that can differentiate between recent and long-term infections (28). Given limitations of the oral fluid HIVST, its package insert describes the window period and the need for CBT if the user suspects infection within the last 3 months (24, 29).

Preferences for oral fluid HIVST and future directions. Across a number of studies and populations, participants prefer oral fluid to blood-based HIVST methods (10, 30–32), likely because the oral fluid method avoids the need to perform a fingerstick (10). A multiregional focus group illustrated that MSM perceive blood specimens as more reliable in detecting HIV than oral fluid, yet there remain concerns that fingerstick blood collection is too complex (10). Fingerstick blood collection

requires the use of an automatic lancet and proper collection of a sufficient amount of blood into a collection medium. When selecting specimen type—oral fluid or fingerstick blood—for HIVST, the potential return rates and preferences of the patient population should be weighed against the sensitivity of the available tests.

There is room for improvement of oral fluid specimen tests, and their popularity demands a more reliable solution. Future options include an increase in performance of oral fluid tests or an increase in acceptability of fingerstick blood self-collection. An example of the former includes antibody detection by agglutination-PCR (ADAP) oral fluid assays, and an example of the latter involves making more full use of blood samples by conducting additional assessments of interest, such as testing for sexually transmitted infections (STIs). Due to the low concentration of HIV antibodies, improving oral fluid test sensitivities has been difficult; however, ADAP is a new technology aiming to increase testing options outside highly specialized clinical laboratories (25). ADAP was developed in 2016 for improved detection of antibody biomarkers for conditions such as type 1 diabetes, autoimmune diseases, and thyroid cancers (10). Recent studies have demonstrated that with ADAP oral fluid sensitivity for HIV is improved up to the standard of other blood-based 3rd-generation tests with clinical sensitivity and specificity of 100% (25). Further development of ADAP oral fluid assays could meet the need for a more accurate oral fluid test method.

In the absence of oral fluid test improvement, increasing the acceptability of a fingerstick test can be achieved by offering additional tests to supplement HIVST because users find the fingerstick more agreeable when other STI tests are offered (33). For example, DBS testing methods have reported high test performance when using self-collected samples for testing HIV, syphilis, and hepatitis B (34). Successful screening for all three requires filling five 15-mm spots on DBS filter paper, which a large majority of testers find acceptable and feasible (34). STI screening with fingerstick blood samples is one option for improving test acceptability; however, this does not solve the issue for those truly opposed to performing a fingerstick, and therefore, when possible, programs should make both options available.

HIGH ACCEPTABILITY OF HIVST AND WILLINGNESS TO PAY

A systematic review of 23 studies by Figueroa et al. reports high acceptability of HIVST among key populations in HIV treatment and prevention (10). MSM in high-income settings find both supervised and unsupervised HIVST to be highly acceptable, with 8 out of 14 studies demonstrating acceptability among more than two-thirds of study participants (10). Acceptability is less studied among certain key populations (e.g., prisoners and populations in low-income settings); however, there is evidence of high acceptability of HIVST among other vulnerable populations, such as female sex workers, people who inject drugs, and transgender women (10). The high degree of acceptability of HIVST among key populations is a strong advantage and argues for the utility of increasing access through appropriate scale-up.

Given high acceptability of HIVST, one potential concern is that HIVST could face high adoption among low-risk populations, thereby limiting the potential benefits. Yet data indicate that uptake of HIVST occurs among those at similar risk profiles as for CBT when tests are offered for free (35) or among those with higher risk profiles than for CBT when high-risk populations are targeted via peer distribution of free kits (36, 37). Therefore, a CBT strategy supplemented by HIVST can reach a greater number of people of higher risk profiles than a CBT-only strategy. Given that CBT is often covered at no cost to the end user by the local health authority, a similar strategy for HIVST merits consideration.

Willingness to pay for HIVST is difficult to compare across studies due to inconsistent measures of price, yet willingness to pay for a single HIVST kit appears overall higher in high-income settings ($20 to $50 per test) than in middle-income ($1 to $20 per test) or lower-income ($0.54 to $4.35 per test) settings (10). Participants were more willing to pay for unsupervised HIVST than for supervised HIVST, which Figueroa et al. hypothesize to be due to the perception that supervised HIVST is similar to CBT, which

is often subsidized in public health care settings. The 2016 American Men's Internet Survey (AMIS) of over 10,000 MSM in the United States found that about 56% of respondents had tested for HIV in the last year (38), which is considerably lower than most estimates of HIVST acceptability (8, 10). This indicates that a substantial barrier to access, such as cost, may be impeding HIVST uptake.

Around 90% of respondents were willing to use HIVST in a 2017 survey of 1,535 individuals in a predominantly African-American neighborhood of Philadelphia, PA, with 3% HIV seroprevalence, yet only 23% of respondents were willing to pay the current U.S. market price ($40) for oral fluid HIVST (8). Assuming that stated willingness to pay in a health research survey likely overestimates actual HIVST purchasing behaviors, market uptake of HIVST is almost certain to be far from optimal. Public funding for HIVST programs would likely improve uptake, and a relevant future research topic is to explore the optimal combination of service provision and subsidy to maximize HIVST uptake among key populations with low or suboptimal levels of recent HIV testing.

SELF-TESTING REACHES FIRST-TIME TESTERS

HIVST can facilitate reaching first-time testers, undertested individuals, and individuals who otherwise would not test for HIV. The ability to reach those who have not previously tested for HIV is paramount in the effort to improve the health of those living with HIV by achieving earlier entry into effective care and carries an additional benefit of reduced forward transmission. Substantial proportions of persons in groups at risk for transmission have either not previously tested or have not tested recently (39). Some of these individuals are undertested, having accessed some prior testing but not meeting clinical guidelines recommended by the CDC (40).

HIVST has been shown to reach a larger proportion of undertested individuals than CBT. Among gay and bisexual men in Australia, undertested individuals are twice as likely to use HIVST as the general population (41). Data from the MSM Testing Initiative in the United States, which recruited testers online with subsequent delivery of test kits by mail, revealed that HIVST with the Home Access Test System was nearly five times more likely to reach first-time testers than CBT (42). Although the Home Access Test System has since been removed from the U.S. market, its popularity among first-time testers would likely extend to other HIVST methods. In an online survey of 5,908 HIV-negative MSM unaware of online HIVST, 86.5% expressed interest in accessing HIVST kits online, indicating convenience and ability to conduct tests at home as the primary reasons (31). Interest in accessing HIVST online was associated with not having been previously tested and not having been tested in the last year (31). In terms of distribution, online orders with home delivery or pickup at a health care facility are equally acceptable methods (41). Online distribution is a common method for promoting HIVST uptake in at-risk populations such as MSM, a natural fit because this group may be more interested in receiving confidential, home-based services (31).

Secondary distribution, the provision of HIVST to individuals who offer tests to personal contacts, reaches a significantly higher degree of first-time testers among African-American and Latino MSM than distribution of HIVST in health care settings (37). Secondary distribution has also been studied among heterosexual persons in Kenya, providing testing kits to HIV-negative female sex workers. Outcomes included a high percentage of couples testing together, a high distribution of testing kits, and a high rate of positive results (43). A survey conducted in the United States discovered that 78% (648/828) of MSM would be willing to distribute free oral fluid or blood-based HIVST kits (44). Among the 648 MSM willing to distribute kits, 73% stated that they would distribute kits to main sexual partners, and 72% stated they would be willing to distribute kits to friends (44). Through novel methods of distribution, HIVST has the ability to reach populations that are traditionally underserved and have a disproportionate risk of HIV infection. Implementation science studies could compare which HIVST distribution methods, online, peer, or clinic-based, reach the greatest number of those not previously tested and at what costs. By tracking which distribution methods

reach higher proportions of undertested and first-time testers, HIVST can be delivered efficiently to a pool of individuals not otherwise connected to the health care system.

DISTRIBUTION OF SELF-TESTING BY PUBLIC HEALTH SYSTEMS

By eliminating cost barriers, public funding for HIVST can facilitate reaching persons of low socioeconomic status or those with economic and transportation barriers. It is appropriate for health systems to subsidize costs of HIVST distribution programs because such programs are likely to be cost-effective. The United Kingdom has redesigned sexual health services in London for delivery via mobile device (mHealth) and thereby transformed the standard of care. The London Sexual Health Transformation Program provides government-funded, free-to-the-public HIVST kits available via online order. Instead of in-person clinic visits, sexual health services preceding HIVST, such as counseling, are online. This is all accomplished with a public-private partnership (45). Appointments for counseling and testing occur by telemedicine at the patient's convenience. Ultimately, the program has integrated sexual health systems across the 32 boroughs of London, increasing access to sexual health services and streamlining the processes of triage and STI testing (45). The program has been estimated to save £30 million to £40 million compared to the prior CBT model (45). Full evaluations of the program are pending, yet London's sexual health system offers a novel case study for the execution of a cost-saving and comprehensive integrated HIVST service.

Other HIVST programs seek to offer services in an online format. RuClear, a confidential testing service for STIs, including HIV, provided in the United Kingdom by the National Health Service mails free test kits to those who order them through their website. Over an 18-month study period with 5,179 testing kits distributed, 59.1% were returned for laboratory interpretation, with most of the kits coming from individuals 16 to 24 years old (46). These data demonstrate the promise of HIVST to reach groups with traditionally lower uptake of CBT, such as those in younger age groups.

HIVST PRETEST COUNSELING

WHO guidelines recommend that pretest counseling or pretest information be made readily available for HIVST (21). A variety of formats are possible, including package inserts, telephone hotlines, phone text messages (SMS), websites, apps, real-time video counseling, and prerecorded online videos; no specific recommendation can be made regarding an optimal method because further research is needed to compare the relative performances and costs of these modalities.

For populations with high levels of prior experience with pretest counseling, lack of counseling is a perceived benefit of HIVST; some MSM described this as an opportunity to avoid unwanted "lecturing" and repetition of messaging that has been experienced before (47). Time-efficient HIVST could potentially produce gains in HIV testing frequency in part by conforming to the CDC recommendation that repeat HIV testing should not necessitate further prevention counseling (48).

Programs serving individuals not previously tested can incorporate pretest counseling using the unique methods for counseling that have been developed for HIVST. Several methods are feasible, and some programs have used preference of the individual tester to determine the provided counseling method. For instance, a study in Thailand among transgender women and MSM found that subjects with concerns regarding confidentiality preferred online pretest counseling (e.g., through video), whereas those with concerns about the quality of HIV care preferred referral to in-person counseling (49). First-time testers indicated a preference for online counseling (49), potentially due to increased privacy. This indicates that multiple avenues for HIVST counseling should be offered when possible.

HIVST POSTTEST COUNSELING AND LINKAGE TO CARE

Antiretroviral therapy (ART) initiation is dependent on whether or not linkage to care is achieved after a positive HIV test. Posttest counseling for HIVST often occurs through information provided in testing kits. OraQuick instructions provide a support number to

call in order to help testers locate "a follow-up health care provider for a confirmatory test" (29). The kit package insert also provides explanations for how false positives and false negatives occur (29). A phone number for the OraQuick support center is offered to help testers who are having trouble or require additional information. Other test kits not currently available in the United States, like atomoRapid, similarly contain step-by-step instructions for result interpretation, providing call lines and a web address for an online video (50).

CBT allows programs to offer linkage to care upon delivery of positive results. For HIVST, the timing (when), targeting (whom), and format (video, audio, or text) of providing linkage to care are less clear. An individual with home-based determination of their result has more power to determine the nature of their engagement with linkage to care services. WHO guidelines recommend that trained personnel provide follow-up services following HIVST, although further evaluation regarding best strategies and approaches is needed (21). Although limited, data on linkage strategies for HIVST indicate suboptimal levels of linkage to care for persons testing positive unless an evidence-based, posttest method of communication is employed (21).

For HIVST, linkage to care strategies may be conducted through a variety of modalities, including active and passive approaches (21). Active approaches involve one-on-one follow-up by trained peer or community health workers. Such follow-up may be in person or via SMS, phone call, or another social messaging platform. Passive approaches utilize information included in test kits to point testers to the next step. Such approaches include brochures and flyers, telephone hotlines, mobile phone messaging services, Internet programs and applications, vouchers and coupons, and appointment/referral cards. WHO guidelines summarize data for each of these processes and suggest that HIVST with appropriate linkage strategies may be effective despite limited data (21).

Although potentially lower linkage to care for HIVST is a major disadvantage, training personnel for improving care linkage has demonstrated success in mitigating this weakness and even turning it into a relative area of strength. A systematic review and meta-analysis of the active linkage approach in Sub-Saharan Africa for HIVST via trained counselors reported a linkage-to-care rate of 95% and an ART initiation rate of 75% (36). Studies in Zimbabwe of active linkage among 1,004 HIV-positive individuals diagnosed at home reported linkage within 4 days as five times more likely when facilitated by a trained advocate via phone call, SMS, or in-person meeting, to remind testers to attend clinic (51). The study notes that trained advocates were persons living with HIV and succeeding with treatment. Randomized control trials in Uganda showed that in-person counseling at home following HIVST resulted in a 2-fold increase in linkage to care and higher levels of ART initiation (52).

A longitudinal study of one passive linkage approach, phone calls initiated by the tester, assessed 896 HIV-negative participants using a post-HIVST call line that sought to promote linkage to care. For this system, which used self-collected specimens sent to a central laboratory for testing, users called a hotline to receive their results, with an automated system for those with indeterminate or negative results and a trained HIV counselor for those with positive results. Among 25 testing positive, 14 were linked to care (56%) (53). This highlights a unique advantage of current blood-based HIVST in which testers are incentivized to call hotlines to receive their results, offering a built-in opportunity for linkage. This is not possible for oral fluid HIVST.

SELF-TESTING AND mHEALTH

Capitalizing on convenience, mHealth has the potential to improve outcomes across the HIV prevention and care continua by increasing HIVST rates. Testing is a necessary first step in accessing the wide spectrum of HIV prevention and treatment services. Phone platforms are able to automate the nature and timing of text messages, increasing the level of communication with testers and potentially increasing testing rates without any additional burden on the health system. One randomized, controlled trial among female sex workers in Kenya found that three weekly text message

reminders about where workers can pick up low-cost HIVST resulted in double the testing rate compared to the same intervention in health care settings during a 2-month follow-up (54). Several mobile app studies, like PrEP@Home and ePrEP, have sought to increase access to HIV preexposure prophylaxis (PrEP) through home testing features, including HIVST (55, 56). Each of these studies sought to minimize the burden of seeking PrEP through a combination of technology-based intervention and home specimen collection to facilitate requisite laboratory tests. Privacy of health information within mHealth apps can be maintained through security protocols, including password-protected access, data encryption, and automated timeouts. mHealth in the form of mobile app services is a natural partner for HIVST, opening possibilities for improved outcomes and facilitating access to combined HIV prevention and treatment service packages.

In the event of a negative result, first-time testers may benefit from posttest interventions. Keep It Up! is one intervention that aimed to reduce STI transmission by offering online video education through enacting various real-life scenarios (57). By recruiting HIV-negative participants from online ads and health care settings, Keep It Up! provided an online video education module for HIV prevention that resulted in lower STI incidence over 12 months (57). Coupled with HIVST, online education could prove an effective posttest counseling and education strategy to maximally use health care resources by minimizing the direct involvement of health care workers.

DISCUSSION

The full potential of self-testing will be realized as it is incorporated into larger testing programs, especially if carefully planned implementation science assessments are built into the program designs. Rather than replacing CBT, HIVST should be viewed as a supplement to clinical care that can reach individuals who otherwise may not have previously tested. Oral fluid testing remains the most acceptable test type due to its simplicity, but enhancing its accuracy would resolve its primary limitation and provide further impetus for its distribution. Fingerstick blood is more accurate but has lower acceptability. Current programs should offer both options if possible, and future research should focus on continuing to improve user acceptability and laboratory test performance.

As of 1 January 2019, the Home Access HIV-1 testing system is no longer for sale, making oral fluid testing via OraQuick the only over-the-counter option on the U.S. market for HIVST (58). In order to encourage competitive pricing and offer the option for blood-based tests with improved accuracy, having more than one FDA-approved HIVST in the United States is an important next step. One alternative, the Insti HIV self-test (59), has recently attained WHO prequalified certification as well as achieving Conformité Européene (CE) marking for clearance in Europe. We anticipate that the manufacturer or others will seek to fill the market gap by seeking FDA approval for a blood-based self-test (60).

Our literature review reporting an overall lower sensitivity of OraQuick than of blood-based HIVST illustrates that currently approved devices in the United States perform less well than those that the FDA has not yet approved. In other words, several self-tests approved in countries outside the United States perform better than the sole self-test currently approved. A lack of superior options in the United States, available elsewhere through approvals such as the CE process, indicates that the FDA review processes may pose a disproportionate barrier to approval. Given the recent U.S. government initiative to end the HIV epidemic, increased flexibility for the FDA to expedite the review of HIV tests with high performance is recommended in order to meet demand and best serve individuals in need of other HIVST options (61).

Whether tests are collected and processed by the user or mailed in to a laboratory, priming people for linkage to care is vital to a successful HIVST system. Without facilitation, users testing positive are less likely to link to care. The concern for linkage favors testing options that require mailing in of specimens to a central laboratory for processing of results, to ensure the opportunity for health care workers to follow up

with any individuals testing positive. In practice, some users may find the wait for results necessitated by mail-in testing to be unacceptable. For home provision of results, call lines for test interpretation and troubleshooting offer individuals the option to discuss results immediately after the test and to receive linkage to care. Moreover, websites of test manufacturers can emphasize counseling resources and offer video explanations for common testing questions. For example, testing services could provide automated multimedia reminders for those using HIVST, providing instructions on how to proceed following specimen collection. Further research into the role of mHealth in posttest counseling could compare online prevention education with standard-of-care posttest counseling.

HIVST affords several unique advantages that can be capitalized on by programs and research. HIV testing is a key entry point into the HIV care and prevention continua, including access to effective treatment, PrEP, PEP, condoms and lubricant, and prevention education. Expanding HIVST initiatives will benefit from funding, political commitment, and further research that weighs the relative benefits and disadvantages of self-testing as the gateway to services. HIVST models of care should be refined based on program and research data that determine the relative performance of different means of test distribution, result reporting (e.g., mail-in reporting versus opt-in call line), and counseling. In sum, research and programs should focus on (i) improving technology of HIVST to increase acceptability/performance, (ii) leveraging HIVST within mHealth programs, and (iii) integrating HIVST with other HIV prevention interventions to create packages of services that can be brought to scale by public health programs. The potential public health impact of HIVST is yet to be fully understood on a large scale. Yet sufficient evidence exists to merit increased funding and support that will allow for program-level data to be collected to understand the health impact of empowering individuals to access this key prevention service.

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